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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,145	12/14/2001	John Shanklin	BSA 02-04	2640
26302	7590	05/04/2004	EXAMINER	
BROOKHAVEN SCIENCE ASSOCIATES/ BROOKHAVEN NATIONAL LABORATORY BLDG. 475D - P.O. BOX 5000 UPTON, NY 11973			SAIDHA, TEKCHAND	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/017,145

Applicant(s)

SHANKLIN ET AL.

Examiner

Tekchand Saidha

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see Advisory.

3. ☐ Applicant's reply has overcome the following rejection(s): see advisory.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1, 3-5 & 60.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

### **Advisory Action**

1. Applicants' Amendment After Final filed 04.12.2004 is Acknowledged. The amendment After Final, however, is **not entered** because it raises new issues that would require further consideration and/or search. Claim 1, recites new limitation 'of at least three-fold' which has no basis in the specification, and a new 'new matter rejection' will have to be made. Further, in view of the additional limitation a new rejection, perhaps that of obviousness will have to be considered. New claim 61, lines 7, 12 & 16, recite 'all of SEQ ID NO : 1 or both of SEQ ID NO : 1', which is confusing, a proper expression would be 'all or both (as the case may be) amino acid positions are with reference to SEQ ID NO : 1. This expression will have be addressed in a new 112 second paragraph rejection.

2. The terminal disclaimer filed on April 12, 2004, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 5,888,790, has been reviewed and is accepted. The terminal disclaimer has been recorded.

The double patenting rejection maintained in the prior Office Action is withdrawn.

### **3. Art Rejection:**

The arguments are not deemed persuasive over those already presented, which claims were and are rejected over the prior art of record.

### **112 Rejection :**

The arguments are not deemed persuasive over those already presented, which claims were and are rejected, for the reasons of record.

4. Rejections (& arguments) made in the prior Office Action (Final) are repeated for Applicants' convenience.

5. ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371 of this title before the invention thereof by the applicant for patent.

Claims 1, 3-5 & 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahoon et al. [PNAS 94 : 4872-4877, May 1997, Reference 1]. Cahoon et al. teach castor mutants or modified  $\Delta^9$ -18:0-ACP desaturase and the crystallographic model of the active sites and variants or mutants. Characterization of specific mutants at positions 114, 117, 118, 179, 181 & 188 are also taught (see the entire document, especially abstract, Fig. 3, and page 4875-column 2). The reference also teaches specific positions which can be replaced by any amino acid or which can be used for making two or more amino acid substitutions in the castor  $\Delta^9$ -18:0-ACP desaturase and having increased activity towards fatty acids having fewer than 18 carbon [see column 5, lines 50-60] All the elements of the claims been taught, the reference anticipates the claims.

6. Claims 1, 3-5 & 60 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.P. 5,705,391 (Cahoon et al., Jan 6, 1998, Reference 2). Cahoon et al. teach mutants or modified  $\Delta^9$ -18:0-ACP desaturase (see column 4, last paragraph) at the identified contact residues M114, L115, T117, L118, G188 & F189, and how these specific positions can be replaced by any other amino acid or which can be used for making two or more amino acid substitutions in the castor  $\Delta^9$ -18:0-ACP desaturase and having increased activity towards fatty acids having fewer than 18 carbon. The reference anticipates the claims.

7. Claims 1, 3-5 & 60 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.P. 5,888,790 (Cahoon et al., filed May 9, 1997, Reference 3). Cahoon et al. teach mutants or modified  $\Delta^9$ -18:0-ACP desaturase (see claims 10-12) at the identified contact residues M114, L115, T117, L118, G188 & F189, and how these specific positions can be replaced by any other amino acid or which can be used for making two or more amino acid substitutions in the castor  $\Delta^9$ -18:0-ACP desaturase and having increased activity towards fatty acids having fewer than 18 carbon. The claims are drawn to any amino acid substitution at the positions indicated and encompass the specific amino acid substitution(s) claimed. All the limitations being taught, the reference anticipates the claims.

Applicants' Arguments (previous) :

Applicants arguments with respect to rejections in items 7-9, lay emphasis upon :  
(1) that single replacement is not claimed in the present invention; (2) references 1 and 3 teach specific double mutants [Ileu118Phe; Pro179Ile in castor  $\Delta^9$ -18:0-ACP

desaturase] which replacements are not being claimed; References 1 & 3 do not provide guidance as to how to arrive at any of the substitutions of the present invention ?; (3) claims of the present invention, as herein amended, are drawn to mutants of castor  $\Delta^9$  -18:0-ACP desaturase having increased activity towards fatty acids having fewer than 18 carbon, said mutant having two or more specifically identified amino acid substitutions, and specification of the present invention provides one of skill in the art with all the necessary guidance to practice the invention as claimed; and (4) summarizing the inventors declaration, it is conveyed from the arguments that of the 800 mutants suggested in the reference only one double mutants could be construed as being suggested by the guidance they have found, and that one would be required to prepare 61 double mutants to discover the double mutant suggested in Reference 1.

In response it is realized that applicants are claiming more than two or more replacements which is encompassed by the one or more replacements taught by the reference(s); and that the specific mutants not being claimed is unimportant, because what the references teach are the specific positions which can be replaced by any amino acid or which can be used for making two or more amino acid substitutions in the castor  $\Delta^9$  -18:0-ACP desaturase and having increased activity towards fatty acids having fewer than 18 carbon [see for example, U.S.P. '391, column 3-5, column 5, lines 50-60]. Further, the references clearly teach not only the specific positions to be modified within the substrate binding groove, but also provide guidance to one skilled in the art to make and use the invention as claimed irrespective of the time involved to repeat the standard protocol in order to make the desired the specific amino acids

substitutions (one or more ; or two or more) at the specific positions taught by each of the references.

8. ***Claim Rejections - 35 USC §112*** (second paragraph)

Claims 1, 3-5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, line 2, recites "substantial increase". The phrase "substantial increase" in claim 1 is a relative term which renders the claim indefinite. The term "substantial increase" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Using a positive expression clearly defining the extent of increase, will overcome this rejection.

Claims 3-5 are included in the rejection for failing to correct the defect present in the base claim(s).

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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May 3, 2004